

**Listing of Claims:**

Claims 1-16. (Cancelled)

Claim 17. (Amended) A system of cytological evaluation of epithelial cells collected from a human breast duct comprising:

a tool ~~or apparatus~~ for accessing a breast duct and collecting breast duct fluid from a human breast while the tool is in the duct;

a chart or written guidelines for evaluating the ductal epithelial cells in the sample for one or more observed indicia selected from the group consisting of cell grouping, cell shape, cell size, nuclear size, nuclear shape, presence or absence of nucleoli, nuclear-to-cytoplasmic ratio, vacuoles in the cytoplasm, cytoplasmic shape, cytoplasmic border, presence or absence of anisonucleosis, presence or absence of mitotic figures, nuclear membrane quality, presence of necrotic debris, chromatin distribution, coarseness of chromatin, and the presence or absence of microcalcifications; and

an algorithm for classifying the sample as being normal, atypical or malignant based on the observed indicia.

18. (Amended) A system as in claim 17, wherein the tool ~~or apparatus~~ for accessing a breast duct comprises a breast duct access and fluid and cell retrieval tool, and one or more of a probe, a tool for administering anesthetic, marking tools for marking an accessed or fluid yielding duct, or a collection receptacle for collecting retrieved fluid and cells.

19. (Original) A system as in claim 17, wherein the algorithm classifies the sample as malignant when the sample is characterized by at least an identifying feature selected from the

group consisting of a loss of cell cohesiveness, loose clusters of epithelial cells, enlarged cells, enlarged nuclei, high nuclear-to-cytoplasmic ratio, increased cytoplasm in some cells, irregular nuclear membranes, clumped chromatin, hyperchromatic chromatin, unevenly dispersed chromatin, enlarged nucleoli, multiple nucleoli, marked variation among the cells of the sample in cell size and nuclear size, necrotic debris, and microcalcifications in background material appearing as dense material with smooth borders and concentric layers or dystrophic and amorphous.

20. (Original) A system as in claim 17, wherein the algorithm classifies the sample as atypical with marked changes when the sample is characterized by at least an identifying feature selected from the group consisting of enlarged ductal epithelial cells, marked nuclear increase in ductal epithelial cells, variation in size and shape of the ductal epithelial cells as compared to normal ductal epithelial cells, abundant cytoplasm in some cells, decreased nuclear-to-cytoplasmic ratios in some cells, coarse chromatin, mild abnormality in chromatin distribution, larger nucleoli than in normal cells, multiple nucleoli, more prominent nucleoli, groups of nuclei that appear to be overlapping, and mitotic figures.

21. (Original) A system as in claim 17, wherein the algorithm classifies the sample as atypical with mild changes when the sample is characterized by at least some of an identifying feature selected from the group consisting of single ductal cells, cohesive multilayered cells, complex groups of cells, monolayered cells, an increased number of cell layers compared to normal cells, increased overlapping of the cells, nuclear crowding of cells, minimally enlarged cells, moderate increase in nuclear size to within a range from about 12 to about 16  $\mu\text{m}$  in diameter, slight anisonucleosis in some cells, and presence of nucleoli.

22. (Amended) A system as in claim 17, wherein the algorithm classifies the sample as normal when the sample is characterized by at least some of an identifying feature selected from the group consisting of single cells, monolayer sheets, tight cells clusters usually having a thickness of one or two cell layers ~~thick~~, small nuclei in a size range from about 8 to about 12

µm in diameter, high nuclear-to-cytoplasmic ratio depending on the orientation of the cells in clusters, in single cells a columnar shape of cytoplasm, in single cells discrete small vacuoles in the cytoplasm, in single cells discrete cytoplasmic border, cohesive groups of ductal epithelial cells with cells of uniform size and regular round to oval shape, monolayer sheets of cells with uniform, small cells, and monolayer sheets of cells with small inconspicuous nucleoli.

23. (Original) A system as in claim 17, wherein the algorithm classifies the sample as insufficient cells to make a diagnosis (ICMD) when the sample has fewer than 10 epithelial cells.

Claims 24-25. (Cancelled)

26. (New) A system of cytological evaluation of epithelial cells collected from a human breast duct comprising:

a tool for accessing the breast duct and collecting a ductal fluid sample from within the breast duct, said tool comprising an elongated portion shaped and sized for extending into the breast duct comprising a single elongated internal lumen through which fluid can be introduced and retrieved from within the breast duct;

a chart or written guidelines for evaluating the ductal epithelial cells in the sample for one or more observed indicia selected from the group consisting of cell grouping, cell shape, cell size, nuclear size, nuclear shape, presence or absence of nucleoli, nuclear-to-cytoplasmic ratio, vacuoles in the cytoplasm, cytoplasmic shape, cytoplasmic border, presence or absence of anisonucleosis, presence or absence of mitotic figures, nuclear membrane quality, presence of necrotic debris, chromatin distribution, coarseness of chromatin, and the presence or absence of microcalcifications; and

an algorithm for classifying the sample as being normal, atypical or malignant based on the observed indicia.